INSURANCE DIVISION[191]

Adopted and Filed

Rule making related to the requirement for pharmacy benefits managers to file annual reports

The Insurance Division hereby amends Chapter 59, "Pharmacy Benefits Managers," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 510.9 and 510B.3 and 2019 Iowa Acts, Senate File 563, section 3.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapters 510 and 510B and 2019 Iowa Acts, Senate File 563.

Purpose and Summary

The Insurance Division (Division) amends current rules in and adds a new rule to Chapter 59 to implement 2019 Iowa Acts, Senate File 563, which requires pharmacy benefits managers to file with the Insurance Commissioner an annual report related to rebates and administrative fees received from pharmaceutical companies and the extent to which those rebates and administrative fees are passed on to the insurance companies for which the pharmacy benefits managers provide services. The legislation, which will be codified as Iowa Code chapter 510C, was signed by the Governor on May 8, 2019, and became effective July 1, 2019.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on June 5, 2019, as **ARC 4482C**. A public hearing was held on June 27, 2019, at 10 a.m. in the Division's offices on the fourth floor of Two Ruan Center, 601 Locust Street, Des Moines, Iowa. Three individuals attended the public hearing, and several individuals participated by telephone.

Two comments were received at the public hearing. The first commenter supported this rule making, stating it would create needed transparency, but also encouraged the Division to continue to evaluate other ways to rein in anticompetitive practices of pharmacy benefits managers (PBMs). In response to this comment, the Division notes that the statute under which the rule making is adopted is limited and does not permit additional requirements. The second commenter remarked that PBMs make drug coverage more affordable for plan sponsors. The commenter also requested clarification as to whether the data collected would be only for regulated health plans located in Iowa and whether the reported data would have some type of Iowa nexus. In response to each of these two questions, the Division states that neither the definitions nor the scope of the statute supports either of those interpretations.

A third commenter expressed support for this rule making at the Administrative Rules Review Committee meeting held on July 9, 2019.

No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by Doug Ommen, Iowa Insurance Commissioner, on July 10, 2019.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

The Insurance Division's general waiver provisions of 191—Chapter 4 apply to these rules.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on September 4, 2019.

The following rule-making actions are adopted:

ITEM 1. Amend rule 191—59.1(510B) as follows:

- 191—59.1(510B,510C) Purpose. The purpose of this chapter is to administer the provisions of Iowa Code chapter chapters 510, 510B and 510C (2019 Iowa Acts, Senate File 563) relating to the regulation of pharmacy benefits managers.
- ITEM 2. Renumber rule 191—59.11(505,507,507B,510,510B,514L) as 191—59.12(505,507,507B,510,510B,514L).
 - ITEM 3. Adopt the following **new** rule 191—59.11(510B,510C):

191—59.11(510B,510C) Pharmacy benefits manager annual report.

- **59.11(1)** *Definitions.* In addition to the definitions set forth in rule 191—59.2(510B), the definitions of Iowa Code section 510C.1 (2019 Iowa Acts, Senate File 563, section 1) shall apply to this rule.
- **59.11(2)** Filing of annual report. In addition to submitting the third-party administrator annual report required under rule 191—58.11(510), each pharmacy benefits manager shall submit to the commissioner on or before February 15 of each year the annual report required by Iowa Code section 510C.2 (2019 Iowa Acts, Senate File 563, section 2) (PBM annual report). The pharmacy benefits manager shall follow the instructions and use the online submission form provided on the Iowa insurance division's website (iid.iowa.gov) to file the PBM annual report.
- **59.11(3)** *Verification.* At least two officers of the pharmacy benefits manager shall certify in writing that they verified the accuracy of the PBM annual report.
- **59.11(4)** *Electronic filing.* Each pharmacy benefits manager shall submit the PBM annual report electronically as set forth in the instructions, unless otherwise specifically authorized by the commissioner.
- **59.11(5)** *Public access*. The commissioner shall publish on the Iowa insurance division's website (iid.iowa.gov) the nonconfidential information received in the PBM annual report.
- **59.11(6)** *Completeness of PBM annual report.* All information required by the commissioner must be submitted before the PBM annual report shall be considered complete.
- **59.11(7)** *Penalties.* A pharmacy benefits manager that fails to timely submit to the commissioner a complete PBM annual report shall pay a late fee of \$100. If a pharmacy benefits manager fails to submit a complete PBM annual report by May 15, the pharmacy benefits manager shall be subject to penalties as set forth in rule 191—59.12(505,507,507B,510,510B,510C,514L).

ITEM 4. Amend renumbered rule 191—59.12(505,507,507B,510,510B,514L) as follows:

191—59.12(505,507,507B,510,510B,510C,514L) Failure to comply. Failure to comply with the provisions of this chapter or with Iowa Code chapters 510, and 510B and 510C (2019 Iowa Acts, Senate File 563), or failure to comply with 191—Chapters 58 and 78 or Iowa Code chapters 507 and 514L as they are relevant to the administration of this chapter or of Iowa Code chapters 510, and 510B and 510C (2019 Iowa Acts, Senate File 563), shall subject the pharmacy benefits manager to the penalties of Iowa Code chapter 507B.

ITEM 5. Amend 191—Chapter 59, implementation sentence, as follows:

These rules are intended to implement Iowa Code chapters 17A, 505, 507, 507B, 510, 510B, 510C (2019 Iowa Acts, Senate File 563) and 514L.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 7/31/19.